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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,096	02/01/2001	Dan Nilsson	54337.000009	6906

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EXAMINER	
STEADMAN, DAVID J	
ART UNIT	**PAPER NUMBER**
1652	

DATE MAILED: 05/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/720,096	NILSSON ET AL.	
	Examiner	Art Unit	
	David J Steadman	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,9-17,24 and 26-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9-17,24 and 26-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

[1] Claims 1-7, 9-17, 24, and 26-32 are pending.

[2] Applicants' amendment to the claims, filed March 09, 2004, is acknowledged. This listing of the claims replaces all prior versions and listings of the claims.

[3] Receipt of a Declaration under 37 CFR 1.132, filed March 09, 2004, is acknowledged. The Declaration has been considered by the examiner.

[4] Applicant's arguments filed March 09, 2004 have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

[5] The text of those sections of Title 35 U.S. Code not included in the instant action can be found in a prior Office action.

Claim Objections

[6] In view of applicant's amendment to claim 26, the objection as set forth in item [7] of the Office action mailed October 09, 2003 is withdrawn.

[7] Claim 6 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim Rejections - 35 USC § 112, Second Paragraph

[8] In view of applicant's amendment to claims 1, 9, 24, 26-27, and 30-31, the rejection under 35 USC 112, second paragraph as set forth in item [9] of the Office action mailed October 09, 2003 is withdrawn.

[9] Claims 1-7, 9-17, 26, 28-29, and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 (claims 2-7, 9-17, 28-29, and 32 dependent therefrom) and 26 recite the limitation "the bacterial starter culture" (see line 2 of part (ii)). There is insufficient antecedent basis for this limitation in the claims. It is suggested that the claim be amended to replace "the bacterial starter culture" with, for example, "a bacterial starter culture."

Claim Rejections - 35 USC § 112, First Paragraph

[10] The written description rejection of claims 1-3, 6-7, 9-17, 24, 26-27, and 30-32 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record as set forth in item [10] of the Office action mailed October 09, 2003 and for the reasons stated below. It is noted that applicants' arguments jointly address the written description and scope of enablement rejections. Applicants' arguments have been addressed herein only to the extent the arguments address the instant written description rejection.

Applicants argue the specification describes a written description of bacterial strains that can be used in the amended method claims. Applicants argue that the genus of recited bacterial strains has been sufficiently described by relevant identifying characteristics. Applicants argue the use of pur- and thyA mutant strains was only exemplary and the specification discloses the use of other non-proliferating strains, citing the examples of "resting cells", "non-dividing cells", and "conditional mutants." Applicants argue the Declaration of Dr. Janzen (hereafter referred to as the "Janzen Declaration") shows the applicability of other bacterial strains to the claimed method and provides an example thereof, citing DNA polymerase mutant strain. Applicants' argument is not found persuasive.

The examiner maintains the position that the two disclosed representative species of bacterial strains, i.e., a purine (Pur-) or thymidine (thyA) auxotrophic bacterial strain that have the ability to replicate in a medium supplemented with purine or thymidine, respectively, but fail to replicate in milk as milk does not comprise sufficient purine or thymidine to support growth of the auxotrophs (see Dickley et al. US Patent 5,691,185, columns 11 and 30), fail to represent the entire genus of recited bacterial strains. Other than these two representative examples, the specification fails to disclose any other representative species by relevant identifying characteristics as defined by MPEP 2163 as follows: "complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics"

and the disclosure of "resting cells", "non-dividing cells", and "conditional mutants" is not a relevant identifying characteristic of the claimed genus as defined by MPEP 2163.

As stated in a previous Office action, MPEP § 2163 states that "[f]or inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus." In this case, the genus embraces widely variant species, which is undisputed by applicants. For example, the genus of bacterial strains of claim 1 encompasses species of bacteria having any alterations that result in a bacterial strain "which is not capable of DNA replication, RNA transcription or protein synthesis in said milk but is metabolically active and thereby enabling acidification of said milk" and has the ability to replicate in a medium other than milk. The Janzen Declaration does not compensate for the deficiencies of the specification in failing to describe the genus of recited bacterial strains and only supports the examiner's assertion that the genus embraces widely variant species. It should be noted that the specification fails to disclose the cited DNA polymerase mutant strain as described in the Janzen Declaration. Even assuming arguendo this example were disclosed in the specification, this example, in addition to the two representative disclosed species, would fail to represent the entire genus of recited bacterial strains, which encompasses widely variant species having any alterations that result in the desired phenotype.

[11] The scope of enablement rejection of claims 1-7, 9-17, 24, and 26-32 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record as set forth in item [11] of the Office action mailed October 09, 2003 and for the reasons stated below. It is

noted that applicants' arguments jointly address the written description and scope of enablement rejections. Applicants' arguments have been addressed herein only to the extent the arguments address the instant scope of enablement rejection.

Applicants argue the specification one of skill in the art to make the full scope of recited bacterial strains that can be used in the amended method claims. Applicants argue the use of pur- and thyA mutant strains was only exemplary and the specification discloses the use of other useful non-proliferating strains, citing the examples of "resting cells", "non-dividing cells", and "conditional mutants." Applicants argue the Declaration of Dr. Janzen (hereafter referred to as the "Janzen Declaration") shows the applicability of other bacterial strains to the claimed method and provides an example thereof, citing DNA polymerase mutant strain. Applicants argue that Dr. Janzen's assertion that "the disclosure... ...is sufficient for me to construct... ...bacterial strains... ...which are useful in the claimed method" is evidence that Dr. Janzen did not have to engage in undue experimentation to practice the various aspects of the claimed invention, Applicants' argument is not found persuasive.

The examiner maintains the position that undue experimentation is required to enable the full scope of the claimed invention. The specification, while being enabling for a method of fermenting milk by: isolating a purine or pyrimidine auxotrophic bacterial strain; propagating the bacterial strain in a medium supplemented with purine or pyrimidine, respectively, to obtain a bacterial starter culture; and adding the bacterial starter culture to milk, wherein the bacterial strain ferments the milk, does not reasonably provide enablement for the broad scope of claimed methods. It is noted that

applicants fail to address the examiner's analysis of the factors of *In re Wands* as set forth in a previous Office action (see item [11] of the Office action mailed October 09, 2003). Nonetheless, it is noted that the claimed methods are so broad as to use any bacterial strain for modifying milk that "is not capable of DNA replication, RNA transcription or protein synthesis in said milk but is metabolically active and thereby enabling acidification of said milk" and having the ability to replicate in any medium other than milk (as recited in claim 1), wherein the bacterial strain is modified by any means such that it possesses the desired characteristic(s). Other than the two disclosed working examples, there is no specific guidance in the specification for any other bacterial strain(s) having the desired characteristics and the Janzen Declaration does not compensate for the deficiencies of the specification in failing to enable the broad scope of recited bacterial strains. In view of the absence of such guidance, a skilled artisan recognizes the high level of unpredictability in altering a bacterial strain (by any method) with an expectation of obtaining a bacterium having the desired phenotype. Even assuming arguendo the example of a DNA polymerase mutant were disclosed in the specification, this example, in addition to the two working examples, would fail to enable the full scope of recited bacterial strains for use in the claimed methods, which broadly encompasses the use of bacterial strains having any alterations that result in the desired phenotype. It is not routine in the art to alter a bacterium by any means available to screen such bacterium for a desired phenotype – in this case, a bacterial strain that is not capable of DNA replication, RNA transcription or protein synthesis in said milk but is metabolically active and thereby enabling acidification of said milk. In

view of the broad scope of the claims, the lack of specific guidance and working examples in the specification, the high level of unpredictability, and the significant amount of experimentation required to make all bacterial strains as used in the claimed methods, a skilled artisan would recognize that undue experimentation is required to practice the claimed invention. As such, the specification does not enable the full scope of claimed methods.

[12] It is noted that the deposit requirement under 35 USC 112, first paragraph for claims 28 and 29 has been satisfied in view of applicant's submission of Declarations of Deposit filed November 14, 2002. It should be noted that one of the Declarations concerning deposit of DSM 12289 is not present in the electronic file. Action is being taken to have this document scanned into the electronic file.

Conclusion

[13] Status of the claims:

- Claims 1-7, 9-17, 24, and 26-32 are pending.
- Claims 1-7, 9-17, 24, and 26-32 are rejected.
- No claim is in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (703) 308-3934. The Examiner can normally be reached Monday-Friday from 7:30 am to 4:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703) 308-3804. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman, Ph.D.

04-29-04